

REMARKS

Claims 1-30 are currently pending in the application. Claims 1, 17, and 27 are in independent form. Claims 2 and 21 are herein canceled without prejudice. Amendments to the claims have support in the canceled claims and other dependent claims, as well as paragraphs [0045] – [0048].

The drawings are objected to because Figures 2 and 3 contain extraneous matter. Figures 1, 4, and 5 are objected to because of areas that are not plain and legible. In response thereto, Applicants submit replacement sheets for those figures. Reconsideration of the objection is respectfully requested.

Claims 1-3, 5, 14, 15, 17, 22, 23, 25, and 26 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,788,676 to Yoon. Specifically, the Office Action holds that Yoon discloses a trocar (10) having an insert end with a housing or “chamber” (14) wherein a pair of universal seals (16a, 16b) are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Yoon, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: “For prior art to anticipate under §102 it has to meet every element of the claimed invention.”

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The goal of the device of Yoon is to prevent damage to universal seals by preventing contact with instruments when they are inserted or withdrawn in the endoscopic portal. More specifically, the universal seals 16a and 16b are "disposed in the main body 26 in axially spaced relation to one another." Col. 6, lines 3-4. In other words, the universal seals are in alignment with one another in order to let an instrument through the portal. One seal is opened allowing passage of the instrument while the other seal remains closed to prevent leakage into the portal.

In contradistinction, as claimed in the presently amended independent claims, the seals of the present invention are perpendicular to each other instead of aligned with each other. This creates a seal around the instrument. Yoon further does not disclose a downflow lumen having an outlet into an instrument lumen. The downflow lumen is used to flow fluid therethrough and into the instrument lumen. The seals being perpendicular to one another are critical for this flush system. The fluid flow through the downflow lumen is able to remove unwanted particles and air bubbles present in the instrument lumen that could harm the patient. It is critical that air not be allowed to enter the bloodstream of a patient. See paragraph [0049] of the present invention. Yoon does not teach a trocar that can perform these important functions.

Therefore, since Yoon does not disclose perpendicular seals and a downflow lumen for removing substances in an instrument lumen as set forth in the presently pending independent claims, the claims are patentable over Yoon and reconsideration of the rejection is respectfully requested.

Claims 27 and 28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,279,551 to James. Specifically, the Office Action holds that James discloses the method steps including the insertion of a stylet (27) into the lumen of a trocar catheter having substance removing means wherein irrigation or suction of fluids is performed through the first lumen or “instrument lumen” (17) or the second lumen via openings (25a, 25b). Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by James, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

James discloses a second lumen 35 having an injection port 45 on the outside or external end of tube 43. “Lumen 34 is spaced radially outward from lumen 17 [the first lumen] ***and they are not connected.***” Col. 4, lines 15-41, emphasis added. James cannot perform the method of the present invention because the two lumens 34 and 17 are not connected. James is merely using the lumen 34 to irrigate the chest cavity or introduce medicine into the chest cavity through opening 41 on the lumen 34. James is not flushing the main instrument lumen in order to remove unwanted substances such as air and other particles. Essentially, James discloses an infusion port that allows various substances to enter the patient.

In contradistinction, the presently amended claims require that flowing fluid through the downflow lumen go into the instrument lumen. The downflow lumen is fluidly connected to the instrument lumen through the outlet port. The fluid flowing from the downflow lumen into the instrument removes the substances such as air from the instrument lumen.

Therefore, since James does not disclose the steps of flowing fluid through a downflow lumen, into the instrument lumen, and removing the substance from the instrument lumen with the fluid as set forth in the presently pending independent claims, the claims are patentable over James and reconsideration of the rejection is respectfully requested.

Claims 4, 18, and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No 5,658,298 to Vincent, et al. Specifically, the Office Action holds that Yoon teaches the device but fails to disclose an O-ring, and Vincent, et al. discloses an O-ring (71) encircling the distal end of the inner shaft within the trocar cannula. Therefore, the Office Action holds that one skilled in the art would have provided an O-ring to the trocar of Yoon as an additional safeguard for preventing deflation of the cavity during use. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Vincent, et al. is respectfully requested.

"Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by

known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 UDPQ2d 1385, 1395 (2007) and MPEP Section 2143.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. Combining Yoon with Vincent, et al. does not make up for these deficiencies.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 6 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No 5,993,471 to Riza, et al. Specifically, the Office Action holds that Yoon teaches the device but fails to disclose perpendicular diaphragms, and Riza, et al. teaches two deformable diaphragms having slits that are perpendicular with respect to one another. Therefore, the Office Action holds that it would have been obvious to one skilled in the art to provide consecutive diaphragms having perpendicular slits to enhance sealing structure. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al. is respectfully requested.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. Combining Yoon with Riza, et

al. does not make up for these deficiencies. Furthermore, the slits in the orientation claimed provide advantages over Yoon's slits. They center the instrument and also provide a fluid tight seal whether or not an instrument is present. See paragraph [0050].

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 7-10, 20, and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of James. Specifically, the Office Action holds that Yoon teaches the device but fails to disclose substance removing means and fluid flow means, and James teaches a trocar catheter having substance removing means wherein irrigation or suction of fluids is performed through the first lumen or "instrument lumen" (17) or the second lumen (35) via openings (25a, 25b). Therefore, the Office Action holds that it would have been obvious to one skilled in the art to provide the trocar of Yoon with the substance removal means and fluid flow means, as taught by James, for the predictable result of channeling fluid away from the patient. Therefore, the Office Action holds that one skilled in the art would have provided an O-ring to the trocar of Yoon as an additional safeguard for preventing deflation of the cavity during use. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of James is respectfully requested.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. James also does not disclose

a downflow lumen in fluid connection with the instrument port that is able to remove unwanted substances from the instrument port. Combining Yoon with James does not make up for the deficiencies in either reference.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No 5,968,060 to Kellogg. Specifically, the Office Action holds that Yoon teaches the device but fails to disclose agitating means that are operatively connected to a trocar, and Kellogg teaches an ultrasonic trocar (10) including a handpiece assembly (50), generator (30), breaking mechanism (130) and an acoustic assembly (80) through which ultrasonic energy propagates to cause vibration within the acoustic assembly. Therefore, the Office Action holds that one skilled in the art would have provided the trocar of Yoon with vibrating means to minimize trauma and detect penetration. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Kellogg is respectfully requested.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. Combining Yoon with Kellogg does not make up for these deficiencies.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No 5,256,149 to Banik, et al. Specifically, the Office Action holds that Yoon teaches the device but fails to disclose a trocar made of plastic being a transparent material, and Banik, et al. discloses a trocar (10) constructed entirely of transparent material. Therefore, the Office Action holds that one skilled in the art would have constructed the plastic trocar of Yoon to be transparent. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Banik, et al. is respectfully requested.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. Combining Yoon with Banik, et al. does not make up for these deficiencies.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 29 stands rejected under 35 U.S.C. §103(a) as being upatentable over James in view of Yoon. The Office Action holds that James discloses all of the

limitations previously discussed except for the method step of sealing the lumen. The Office Action holds that it would have been obvious to provide the trocar of James with sealing means as taught by Yoon. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over James in view of Yoon is respectfully requested.

As stated above, Yoon does not disclose all of the required elements of the presently pending independent claims of having perpendicular seals and a downflow lumen for removing substances in an instrument port. James also does not disclose a downflow lumen in fluid connection with the instrument port that is able to remove unwanted substances from the instrument port. Combining Yoon with James does not make up for the deficiencies in either reference.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over James in view of Kellogg. The Office Action holds that James fails to teach agitation means, but it would have been obvious to have provided James's trocar with vibrating means as taught by Kellogg. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Banik, et al. is respectfully requested.

As stated above, James does not disclose all of the required elements of the presently pending independent claims of the steps of flowing fluid through a

downflow lumen, into the instrument lumen, and removing the substance from the instrument lumen with the fluid. Combining Yoon with Kellogg does not make up for these deficiencies.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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